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EXAMINER

ROBINSON, KEITH O NEAL

| ART UNIT | PAPER NUMBER |
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| 1638 | |

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Claims 19-26 and 28-32 have been cancelled.

Claim Objections

Claims 1, 8, 17, and 43 are objected to for the inclusion of blanks (____). It is assumed that the blanks will be replaced by an ATCC Accession Number.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 27, and 33-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to inbred sunflower seed H1063R, methods of making and/or using said sunflower seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be

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readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. It is noted that Applicants have deposited the seed of inbred sunflower seed H1063R with Agrigenetics, but such a deposit appears not to have been made with the American Type Culture Collection in Manassas, Virginia. Furthermore, there is no disclosure as to the period of time the deposit will be maintained, no mention of a test of viability, nor a statement indicating that the deposit will be replaced if it becomes inviable. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

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- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807)I and,
- (e) the deposit will be replaced if it should ever become inviable.

Claims 11-18 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 11-16 are broadly drawn to hybrid sunflower seeds or plants developed by the crossing of sunflower plant H1063R with another sunflower plant. The claims seem to include any hybrid plant derived from the crossing of H1063R with any sunflower plant.

The specification does not describe the other sunflower plant or plants that are to be crossed with H1063R nor is there a description of their genetic

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background. It is known in the art that any plant derived from the crossing of two different plants will give a hybrid F1 plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the H1063R sunflower plant and 50% of the alleles from the other sunflower plant. The H1063R sunflower plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the H1063R sunflower plant is not the same as the claimed H1063R sunflower plant, which would have 100% of its alleles. Furthermore, claims 13 and 16 read on an additional generation of outcrossing to a non-H1063R sunflower parent so that seed with as little as 25% of the H1063R alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing H1063R with any sunflower plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids.

Claims 17-18 are broadly drawn to a method for producing inbred H1063R by planting hybrid seed whose pedigree consist of H1063R as well as planting H1063R, growing these plants, identifying inbred parent plants, controlling pollination to preserve homozygosity, and harvesting seed.

As discussed previously, the hybrids are not described in the specification and do not contain the full complement of alleles as the claimed inbred, H1063R. There is no description in the specification of any inbred parent plants as claimed

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in step (c) as to their genetic, morphological, and/or physiological characteristics nor is there a description of pollination control for the preservation of homozygosity as claimed in claim step (d).

Claim 27 is broadly drawn to the transformation of the sunflower plant of claim 2 so that its genetic material contains a transgene operably linked to a regulatory element. The claim seems to infer the use of any transgene.

The specification does not describe the multitude of broadly claimed transgenes and they have not been characterized with regard to sequence or conferred trait. The specification also does not describe how to identify the claimed sunflower plants from a collection of other plants.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials”. *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material”. *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus”. *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claims 43-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims make reference to and/or are dependent upon claims which recite a "5% significance level when grown in the same environmental conditions", and there does not appear to be literal support in the specification for this term. Accordingly, the claims are directed to NEW MATTER.

Claims 11-18 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11-16 are broadly drawn to hybrid sunflower seeds or plants developed by the crossing of sunflower plant H1063R with another sunflower plant. The claims seem to include any hybrid plant derived from the crossing of H1063R with any sunflower plant.

The specification does give any guidance as to the other sunflower plant or plants that are to be crossed with H1063R nor is there any guidance as to their genetic background. It is known in the art that any plant derived from the crossing of two different plants will give a hybrid F1 plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the H1063R sunflower plant and 50% of the alleles from the other sunflower plant. The H1063R sunflower plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the H1063R sunflower plant is not the same as the claimed H1063R sunflower plant, which would have 100% of its alleles. Furthermore, claims 13 and 16 read on an additional generation of outcrossing to a non-H1063R sunflower parent so that seed with as little as 25% of the H1063R alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed

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hybrids are not disclosed in the specification. Since the claimed invention is derived from crossing H1063R with any sunflower plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

Claims 17-18 are broadly drawn to a method for producing inbred H1063R by planting hybrid seed whose pedigree consists of H1063R as well as planting H1063R, growing these plants, identifying inbred parent plants, controlling pollination to preserve homozygosity, and harvesting seed.

As discussed previously, the hybrids are not described in the specification and do not contain the full complement of alleles as the claimed invention, H1063R. There is no guidance in the specification of any inbred parent plants as claimed in step (c) as to their genetic, morphological, and/or physiological characteristics, i.e. how to use said inbreds; nor is there any guidance in regards to pollination control for the preservation of homozygosity as claimed in claim step (d); i.e. how to make said inbreds.

Claim 27 is broadly drawn to the transformation of the sunflower plant of claim 2 so that its genetic material contains a transgene operably linked to a regulatory element. The claim seems to infer the use of any transgene.

The specification does not provide any guidance as to the multitude of broadly claimed transgenes nor have they been characterized with regard to

sequence or conferred trait. The specification also does not provide guidance as to how to identify the claimed sunflower plants from a collection of other plants, or how to use said plants containing unspecified transgenes.

While the introgression of single genes into plants for a desired trait is desirable and is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al. (US Patent No. 5,523,520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that did not result in the expected transfer gene trait (see, column 3, lines 26-46). Kraft et al. (Theoretical and Applied Genetics 101:323-326, 2000) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait and that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (see, page 323, column 1, lines 7-15). Eshed et al. (Genetics 143:1807-1817, 1996) teach that epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, pages 1815-1816).

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Finally, in a study of sunflower, Perez-Vich et al. (Theor Appl Genet 100: 105-111, 2000) teach that epistatic effects occur between loci (see, page 110, second column, lines 2-17).

Furthermore, the use of backcrossing in plant breeding is unpredictable. Zeven et al (Euphytica 32 : 319-327, 1983) teach that linkage drag is very common in backcross breeding (see pages 325-327) and Young et al (Theor Appl Genet 77: 353-359, 1989) teach that “backcross breeding is only moderately effective in reducing linkage drag around gene targets” (see page 357, first column, second full paragraph); therefore it is unpredictable which useful traits will be retained.

Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in sunflower breeding materials, such that one or more genes can be transferred from one genetic background to another, wherein the resultant sunflower progeny would either express the desired trait or maintain all of the other desirable H1063R genes and traits.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue experimentations.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to the sunflower plant H1063R that has been transformed to contain a transgene operably linked to a regulatory element.

The claim does not particularly point out the transgene that is claimed nor does it characterize what trait is conferred by said transgene.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole (US Patent No. 5,866,766, February 2, 1999). The claims read on F2 progeny, including segregating progeny with 100% of non-H1063R alleles; therefore, the claims read on any sunflower plant or seed with any alleles at any locus. The claimed method of making the plant or seed (by selfing a hybrid

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sunflower plant) would not confer a unique property to the resultant non-H1063R sunflower plant or seed. Cole teaches a sunflower plant and seeds thereof (see column 6, lines 15-67 to column 7, lines 1-62).

The sunflower plant or seed taught by the prior art differs from the claimed sunflower plant or seed in their method of making, namely by use of different parental material. However, the method of making the claimed sunflower plant or seed would not distinguish them from the prior art sunflower plant or seed. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-12, 14, 15, 17-18, 27, and 33-47 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified sunflower plant which possesses a unique genetic complement and unique collection of traits as that of sunflower plant H1063R, or methods of using it. The closest prior art, Cole (US Patent No. 6,069,304, May 30, 2000) teaches a sunflower plant with narrower than long leaf width; full branching; acuminate, auriculate, medium serrate, and crinkled leaves; green leaf color and margin color; ray flowers that

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are present; yellow ray flower and disk flower color; green pappi; seed with a white middle pericarp, no color inner pericarp, mottling absent, and curved shape; and susceptibility to verticillium wilt and downy mildew (see Table 1, columns 9-10). Cole does not teach a sunflower plant with leaves with a lanceolate leaf shape, shallow depth margin, or ascending attitude; seeds with a striped brown outer pericarp and narrow white stripes; or susceptibility to sclerotinia wilt, phoma black stem, phomopsis, sunflower moth, banded sunflower moth, seed weevil, sunflower midge, or sunflower beetle.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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August 27, 2004

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.